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September 29, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act -- Docket #98D-0265

Dear Sir or Madam:

On behalf of our client, Arnall Golden & Gregory, LLP (AG&G) submits these comments in response to the Food and Drug Administration's issuance of the guidance document entitled, "Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act." FDA released the document in June 1998 to offer guidance to the pharmaceutical industry on how the Agency intended to implement Section 111 of the Food and Drug Administration Modernization Act of 1997 (hereinafter the "Modernization Act"), which created Section 505A of the Federal Food, Drug, and Cosmetic Act (the "FDC Act"), 21 U.S.C. § 355A. For the reasons to be discussed, AG&G recommends that FDA clarify its position relating to multiple grants of pediatric exclusivity.

Section 505A provides 6 months of exclusivity for a drug whose manufacturer conducts specific clinical studies (which, at the Secretary of Health and Human Services' discretion,[1/] may include pharmacokinetic studies) in pediatric populations.[2/] Pediatric exclusivity can only augment

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1/ In Section III.A. of its guidance document, FDA states that the agency may make this determination.

2/ We will not describe the statutory conditions for receiving this additional period of exclusivity.

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existing exclusivity, such as 3 or 5 years of exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as "the Waxman-Hatch Act" for its primary Congressional sponsors), orphan drug exclusivity, or patent protection.

The Modernization Act limits the 6-month exclusivity period to one grant per drug product. FDA may nevertheless award an extra 6 months of exclusivity if the applicant submits a supplemental new drug application ("sNDA") for a second pediatric study in accordance with the statutory requirements. 21 U.S.C. § 355A(h). However, the Modernization Act states that FDA may not add this second 6-month period to patent protections or orphan drug exclusivity afforded under the FDC Act; the additional period of pediatric exclusivity may attach to 3 years of Waxman-Hatch exclusivity. Id.

Congress made clear that one 6-month period of pediatric exclusivity may be added to 5-year Waxman-Hatch exclusivity. 21 U.S.C. § 355A(c). However, for reasons not explained in the Modernization Act or in its legislative history, Congress did not indicate whether a second 6-month period of pediatric exclusivity could attach to a 5-year exclusivity period.

Without any elaboration, FDA stated in Section X.B. of its guidance document that:

> A second pediatric study meeting the statutory requirements described in this guidance and submitted in a supplemental application for a drug that has already received one period of pediatric exclusivity may qualify the drug to receive one additional period of exclusivity. The one additional period of pediatric exclusivity will attach only to any exclusivity period under Sections 505(c)(3)(D)(iii) and (iv) and 505(j)(5)(D)(iii) and (iv) [3-year exclusivity provisions].

Based on this statement, it appears that, according to FDA, a firm whose drug product is covered by 5-year Waxman-Hatch exclusivity may obtain only one additional period of pediatric exclusivity, even if the firm were to conduct a second pediatric study that met the statutory requirements. We have confirmed this understanding through informal discussions with Agency officials. FDA takes this position, despite nothing in the Modernization Act to support this interpretation.

We believe that a second 6-month exclusivity period should attach to a drug product that has obtained 5 years of exclusivity when the NDA holder has complied with the other statutory requirements. For example, a company with 5-year exclusivity might conduct one pediatric study,

submit an sNDA and receive 6 months of exclusivity. However, it might not be possible to obtain sufficient information to adequately describe all aspects relating to the use of a drug in pediatric patients from one study. If the company conducts a second study, in accordance with the statutory requirements, that is different from the first study in order to further determine the use of the product in a broader pediatric population, demonstrate the product's long-term safety and efficacy, assess a new indication to expand the drug's use, evaluate a new formulation, or generate pharmacokinetic information, the company should receive a second period of 6-month exclusivity. Thus, the company might ultimately receive 5 years of Waxman-Hatch exclusivity plus two 6-month periods of pediatric exclusivity. This additional period is justified and furthers the Congressional intent to provide an incentive for companies to generate additional information that may produce health benefits in the pediatric population.

In the alternative, FDA should provide that a company with 5 years of Waxman-Hatch exclusivity may receive one 6-month exclusivity period for one pediatric study, submit an sNDA for a new indication or a modification to the drug product which expands the population use or conditions for use (or adds or strengthens an instruction about dosage and administration that is intended to increase the safe use of the product), thereby requiring a labeling change (see, e.g., 21 C.F.R. § 314.70(b)(3), (c)(2)), receive 3 years of Waxman-Hatch exclusivity for the sNDA (assuming the conditions for exclusivity are met), and then obtain a separate 6-month exclusivity period if the company conducts a pediatric study related to the sNDA product (assuming compliance with the pediatric exclusivity provisions). Of course, this new 6-month exclusivity period would apply only to the new product indication or modification that necessitated the sNDA, and would not apply to the entire drug product, covered by the initial 5-year exclusivity, which distinguishes this case from the scenarios described above, where two 6-months periods of exclusivity would attach to 5-year Waxman-Hatch exclusivity.

For the reasons discussed, we request that FDA clarify its position on multiple grants of exclusivity and its relationship to 5-year Waxman-Hatch exclusivity, and incorporate our recommendations when it finalizes its guidance document. We also ask FDA to consider our comments submitted to Ms. Khyati Roberts, the Project Manager of FDA's Pediatric Subcommittee, dated April 16, 1998, which have been put in this docket.

We appreciate the opportunity to submit these comments. Please feel free to contact us if you have any questions.

Sincerely yours,

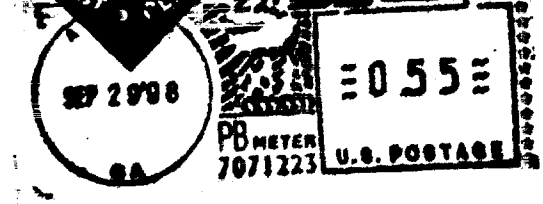
ARNALL GOLDEN & GREGORY, LLP

Alan Minsk

Alan G. Minsk

AGM:mkm

cc: Ms. Khyati N. Roberts
Executive Operations Staff (HFD-6)
Center for Drug Evaluation and Research
Food and Drug Administration



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